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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,125

07/08/2003

Axel Grandt

17601.19.1

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57360

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06/09/2009

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,125	Applicant(s) GRANDT, AXEL	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,15-17,21-23 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,15-17,21-23 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "the third circumferential ring" in lines 1,2 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not require that there are 3 rings.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,5-7,26-29,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. (6758859) in view of Brown et al. (6071305). Dang et al. disclose (Fig. 4) a stent having a plurality of tubular members **22**, each tubular member being formed into a circumferential ring having a plurality of upper peaks and lower peaks and the adjacent circumferential rings being coupled to one another. It can also be seen each tubular member having one or more hollow core sections **30**. Dang additionally discloses the core sections contain a therapeutic agent, col. 5, lines 10-62. Dang also discloses variations in stent design,

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col. 9, lines 26-28 and as seen in Fig. 1, the lower peak of one ring is connected with the upper peak of an adjacent ring and it can be seen there are at least 3 rings. However, Dang et al. fail to disclose a multiplicity of pores providing fluid communication between the one or more hollow core sections and the external environment. Brown et al. teach (Fig. 6) a stent with core sections **20** filled with therapeutic material **23** and the stent having a plurality of pores **28** in communication with the core sections. It would have been obvious to one of ordinary skill in the art to incorporate a plurality of pores for elution control from the stent as taught by Brown et al. with the stent of Dang et al. such that the proper release is given to the patient for particular drugs or therapeutic agents. Thus, the stent core sections are configured to elute agents from the one or more hollow core sections in a controlled manner into the vessel through the multiplicity of pores after implantation of the stent within the vessel. Regarding claims 5,7 Brown et al. also teach that the pore size and number can be varied to control elution rate, col. 9, lines 30,31. Thus, it would have been obvious to optimize and vary the distance, see Fig. 8 of Brown. With respect to claim 6, it is inherent that the pores are disposed about the circumference since Dang has core sections disposed about the ring members. Regarding claim 26, Dang discloses one ring can have a first therapeutic agent and second ring can have a second therapeutic agent, col. 6, lines 9-11. With respect to claim 28, Dang discloses the stent is balloon expandable, col. 7, lines 65-67. Regarding claim 29, Dang discloses the therapeutic agent can be in a polymer, col. lines 11,12 and it is known that the polymers are bioabsorbable, col. 2, lines 11-13.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. '859 in view of Brown et al. '305 as applied to claim 1 above, and further in view of Harry (2002/0038146). Dang et al. as modified by Brown is explained supra. Brown does disclose the

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pores can be any type of opening or shape, col. 6, lines 15-18. However, Dang et al. in view of Brown fail to disclose the pores vary in size or shape with respect to one another. Harry teaches (Figs. 2,3) pores varying in size on the stent. Harry also teaches (Fig. 8) pores that vary in shape on the stent. It would have been obvious to one of ordinary skill in the art to vary the size or shape of the pores as taught by Harry with the stent of Dang as modified by Brown to provide different amounts of therapeutic material released from the stent.

Claims 1,2,5,6,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al. (5882335) in view of Fontaine (5443498) and Brown et al. (6071305). Leone et al. illustrate (Figs. 1,2) a stent **12** formed of a tubular member **28** with a lumen therein and a multiplicity of pores **29** in fluid communication with the lumen. Leone also discloses a therapeutic agent is delivered into the lumen via the proximal end (col. 3, lines 47-49) and is eluted from the stent into the vessel it is implanted in, col. 3, lines 61-65. Leone does disclose other stent designs can be used, col. 4, lines 38-40. However, Leone et al. fail to explicitly disclose the stent is a plurality of tubular members with circumferential rings having upper peaks connected to lower peaks of adjacent tubular members or the material containing the drug is a bioabsorbable polymer. Fontaine teaches (Figs. 5,12) a stent with a plurality of tubular members having circumferential rings with the peaks and valleys of adjacent rings coupled together. Fontaine also teaches that the ring structures provide more rigidity and less likely to pulsate or rub in the vessel, col. 2, lines 36-42, col. 3, lines 63-66. Brown et al. teach (Fig. 2) a stent with circumferential sections including a channel **20** for therapeutic material. Brown discloses that bioabsorbable polymers (col. 8, lines 62-65, col. 9, line 1, col. 10, lines 19-21) are used as means for controlling release from the channel into the lumen of the patient. It would have been obvious

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to one of ordinary skill in the art to use a absorbable polymer to hold the drug as taught by Brown et al. disposed in the tubular members of the stent of Leone et al. as modified by Fontaine to have a plurality of circumferential rings to increase the strength of the stent to maintain lumen patency. Regarding claim 5 the distance between the first pore and second pore would be spaced apart at a distance different than the first pore to the third pore.

Claims 15-17,21,22,30,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. '859 in view of Brown et al. '305 and Tower et al. (EP 1057460). Dang et al. as modified with Brown is *explained supra*. However, Dang et al. in view of Brown also fail to disclose the step of "coupling the circumferential rings" although the rings are coupled together. Tower et al. teach (Fig. 2) a stent where individual circumferential rings **21** are coupled together at welds **40** where a lower peak of a ring is coupled to the upper peak of an adjacent ring. It would have been obvious to one of ordinary skill in the art to couple circumferential rings as taught by Tower et al. with the stent of Dang as modified by Brown to provide the necessary length of stent for a particular vessel by coupling the necessary amount of rings to produce the desired length. Regarding claim 16, since the rings are positioned circumferentially and are from proximal to distal end, it can be interpreted that there is therapeutic material at the "proximal opening" since Dang discloses to place therapeutic material in each ring. With respect to claim 17, Dang discloses the stent is made from shape memory alloys, col. 4, lines 23-36. Claims 21,22,30,31 are explained above with respect to Dang.

Response to Arguments

Applicant's arguments with respect to claims 1,15 have been considered but are moot in view of the new ground(s) of rejection. Additionally, Applicant's arguments filed 2/25/09 have been fully considered but they are not persuasive. Applicant argues that Fontaine makes the rings a different way than the Applicant's claimed invention. A comparison of process of how the Applicant makes the stent with the prior art processes does NOT serve to resolve the issue of concerning patentability of the product of claims 1 and 23. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case product-by-process claims are not construed as being limited to the product formed by the specific processes recited. In re Hirao, 535 F2d 67, 190 U.S.P.Q. 15 see footnote 3 (CCPA 1976). Claims 1 and 23 are not methods of making or manufacture and that the rings have to be separate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738